REMARKS

Applicant has carefully studied the nonfinal Examiner's Action mailed December 13, 2006, as well as the Decision of the Board of Patent Appeals and Interferences. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Claims Objections

Applicant gratefully acknowledges informalities found by the Examiner. Applicant has removed the "an" from claims 12 and 13, thereby addressing Office's objections. As such, Applicant respectfully requests Office withdraw the objection to claims 12 and 13.

Claim Rejections - 35 U.S.C. § 112, 1st paragraph

Written Description

Claims 9 and 11-13 stand rejected for failing to comply with the written description requirement. The Office found the claimed invention is directed to methods of modulating tumors using Oct-1 inhibitors, which provide both increasing and decreasing tumor growth.[1] Further, the Office found nothing in the disclosure which indicates inhibiting Oct-1 results in increased tumor growth. Applicant respectfully notes that amended claim 1 provides "[a] method for treating a malignant neoplasm[,]"[2] not modulating tumor. Thus, the amended claims do not include increasing tumor growth through Oct-1 inhibition, but rather require Oct-1 inhibition to treat, i.e. decrease, the neoplasia.

The Office also noted that the claimed invention is drawn to preventing Oct-1 function, which the Office concluded means "to stop from occurring," but that no inhibitors disclosed fully prevent Oct-1 function.[3] As noted above, the amended claims provide a method of treating, which is defined as "giv[ing] aid to counteract[.]"[4] The Office noted that the specification provides that the Oct-1 inhibitors result in decreased cancer growth.[5] As such, the administration of Oct-1 inhibitor counteracts the neoplasia, i.e. decreases cancerous growth.

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[1] Page 4 of the non-final Office Action, dated February 2, 2006 (Arguments incorporated on Page 3 of the final Office Action, dated December 13, 2006).
[2] See, page 2, claim 9, Amendment A, filed June 2, 2006; page 2, amended claim 9, herein.
[3] Page 4 of the non-final Office Action, dated February 2, 2006 (Arguments incorporated on Page 3 of the final Office Action, dated December 13, 2006).
[4] http://dictionary.reference.com (searched treating) (Last accessed February 11, 2009).
[5] Page 4 of the Examiner's Answer, mailed January 24, 2008.

The Office also stated "neither the specification nor prior art describe any inhibitors of Oct-1 that treat tumors in a subject."[6] MPEP 2163(I)(A) provides "[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." The written description requirement serves to inform the public that the inventor has invented the claimed subject matter,[7] and requires that the application describe the claimed invention sufficiently that a skilled artisan would conclude the inventor possessed the invention at the time of filing.[8] Applicant notes that the Office withdrew its written description rejection of claims 12 and 13.[9] Claims 12 and 13 provide

> 12. The method of claim 9 wherein the Oct-1 inhibitor is a vector containing an Oct-1 antisense sequence.
>
> 13. The method of claim 9 wherein the Oct-1 inhibitor is an RNA inhibitor molecule.

and therefore provide a method of treating neoplasm by administering an Oct-1 antisense vector or Oct-1 RNA inhibitor molecule, respectively.[10] By withdrawing the written description rejection of claims 12 and 13, the Office has acknowledged the specification provides adequate support for at least *in vivo* cancer treatment using Oct-1 antisense vector or Oct-1 RNA inhibitor molecule. Further, Applicant has amended claim 9, limiting the claims to nucleotide Oct-1 RNA inhibitors. The Board of Patent Appeals and Interferences further noted that

> [a]ppellants were apparently the first to show that targeting Oct-1 mRNA function with an antisense molecule decreased cell proliferation in vitro. There is no Oct-1-specific evidence in the record that lead us to expect results differing from those achieved by targeting other cancer molecules in vivo.[11]

As such, Applicant respectfully submits that the application does disclose the use of nucleotide inhibitors of Oct-1 to treat tumors in a subject.

Finally, the Office found the claimed invention encompasses any substance that can inhibit Oct-1 mRNA function, including oligonucleotide, ribozyme, siRNA, non-nucleic acid

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[6] Page 4 of the final Office Action, Dated December 13, 2006.
[7] MPEP 2163(I).
[8] MPEP 2163(I) (citing *Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 U.S.P.Q.2d 1429 (Fed. Cir. 2003). See also, *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000); *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.90 (CCPA 1976).
[9] Page 3 of the Examiner's Answer, mailed January 24, 2008.
[10] MPEP (dependent claims incorporate the elements of the independent claim)
[11] Page 16 of the BPAI Decision on Appeal, decided December 22, 2008.

inhibitors.[12] Applicant has amended the claims to provide that Oct-1 inhibitor is a nucleotide,[13] thereby rending the rejection moot and presents the following comments in support of patentability of the claims.

The Office acknowledged two vectors of antisense nucleotides decreased cell growth compared to a control,[14] but contends the Oct-1 oliognucleotide is not representative of the claims, which include ribozyme, siRNA, non-nucleic acid inhibitors.[15] The BPAI agreed, finding that "the only known or disclosed inhibitors of Oct-1 mRNA function have a nucleic acid structure[.]"[16] Applicant has accordingly revised the claims to cover only nucleotides. "Mention of representative compounds encompassed by generic claim language clearly is not required by §112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification … mention of representative compounds may provide an implicit description upon which to base generic claim language."[17] The present invention explicitly discusses nucleotide inhibitors and provides a working example of a nucleotide inhibitor, an antisense sequence. Moreover, the BPAI noted that the disclosure of the antisense molecule "may be representative of other nucleic acid molecules[.]"[18]

Accordingly, it is respectfully requested that the 35 U.S.C. § 112, first paragraph written description rejection of claims 9 and 11-13 be withdrawn.

Enablement

Claims 9 and 11-13 were rejected by the Office as failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully notes the Board of Patent Appeals and Interferences found claims 9 and 11-13 do comply with the written description requirement.

Accordingly, Applicant respectfully requested that withdraw the 35 U.S.C. § 112, first paragraph enablement rejection of claims 9 and 11-13.

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[12] Page 4 of the Examiner's Answer, mailed January 24, 2008.
[13] See, page 2, amended claim 9 herein.
[14] Page 4 of the Examiner's Answer, mailed January 24, 2008.
[15] Page 5 of the Examiner's Answer, mailed January 24, 2008.
[16] Page 8 of the BPAI Decision on Appeal, decided December 22, 2008.
[17] *Univ. of Cal. v. Eli Lilly and Co.*, 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) (Citing *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618)
[18] Page 6 of the BPAI Decision on Appeal, decided December 22, 2008.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN

/thomas e toner/

By:_____

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Dated: February 23, 2009
Customer No. 21,901

CERTIFICATE OF MAILING
(37 C.F.R. 1.8 (a))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on February 23, 2009.

/lauren reeves/

Lauren Reeves

Dated: February 23, 2009